

Amendment And Response
Serial No. 10/726,324

REMARKS

Claims 1-6, 11-14, 17-19, 24-26 and 29-42 are pending in the present application. By this Amendment, the specification has been amended; previously presented claims 1-6, 11-14, 17-19, 24-26 and 29-30 have been amended; previously presented claims 7-10, 15-16, 20-23 and 27-28 have been canceled; and new claims 31-42 have been added.

Support for the amendments to previously presented claims 1-2, 4, 14, 17-18 and 29-30 may be found in at least the following locations of Applicants' original specification: page 8, lines 15-22, and FIG. 5 (claims 1, 17 and 30); page 7, lines 10-16, and FIG. 2 (claims 2, 4 and 18); and page 9, lines 1-4, and FIG. 5 (claims 14 and 29).

Applicants respectfully request reconsideration of the present claims in view of the foregoing amendment and the following remarks.

I. Formal Matters:

Objection To Drawings:

A new set of drawings is being submitted along with the present Amendment and Response in order to (1) remove the reference character "42" from FIG. 4, and (2) incorporate the reference character "10" into FIGS. 2 and 6. Entry of the new set of drawings and withdrawal of the present objection is respectfully requested.

Objection To Specification:

Regarding the error in the original specification at page 6, line 10, as shown above, this paragraph has been replaced with a corrected paragraph.

Applicants do not understand the objection of the specification with regard to the use of the phrase "a second portion" in claim 6, line 2 and "the second portion" in claim 6, lines 3-4. "A second portion" as used in claim 6, line 2 provides antecedent basis for "the second portion" as used in claim 6, lines 3-4. Further, this embodiment is clearly supported by language in at least the following locations of the original specification: paragraph [0020] from page 7, line 10 to page 8, line 5, and FIG. 2.

For at least the reasons given above, Applicants respectfully request withdrawal of the objection to the original specification.

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Provisional Obviousness-Type Double Patenting Rejection

Previously presented claims 1-4, 6, 15, 17-18, 25-26 and 29 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of co-pending U.S. Patent Application Serial No. 11/298,251. Since the presently presented claims and the claims of co-pending U.S. Patent Application Serial No. 11/298,251 are still pending, Applicants respectfully submit that further action at this time is unwarranted. However, Applicants will consider filing a terminal disclaimer in the present application and/or co-pending U.S. Patent Application Serial No. 11/298,251 as necessary to avoid the possibility of double patenting. Applicants would be glad to discuss this matter with Examiner Jackson in a telephone interview prior to the next office communication.

Previously presented claims 5 and 7-9 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of co-pending U.S. Patent Application Serial No. 11/298,251 in view of U.S. Patent No. 5,197,493 issued to Grier-Idris (hereinafter, "Grier-Idris") and U.S. Patent Publication No. 2002/0108615 to Levitt et al. (hereinafter, "Levitt"). Applicants respectfully submit that there is no suggestion in the art of record to modify the drape as disclosed in claims 1-5 of co-pending U.S. Patent Application Serial No. 11/298,251 as suggested by Examiner Jackson. However, even though Applicants disagree with Examiner Jackson's position, Applicants will consider filing a terminal disclaimer in the present application and/or co-pending U.S. Patent Application Serial No. 11/298,251 as necessary to avoid the possibility of double patenting.

Previously presented claims 19-20, 22 and 30 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-20 of co-pending U.S. Patent Application Serial No. 11/298,251 in view of Grier-Idris and Levitt. Applicants respectfully submit that there is no suggestion in the art of record to modify the drape as disclosed in claims 18-20 of co-pending U.S. Patent Application Serial No. 11/298,251 as suggested by Examiner Jackson. However, even though Applicants disagree with Examiner Jackson's position, Applicants will consider filing a terminal disclaimer in the present application and/or co-pending U.S. Patent Application Serial No. 11/298,251 as necessary to avoid the possibility of double patenting.

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Previously presented claims 10-14 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of co-pending U.S. Patent Application Serial No. 11/298,251 in view of Grier-Idris and U.S. Patent No. 5,225,236 issued to Keusch et al. (hereinafter, "Keusch"). Applicants respectfully submit that there is no suggestion in the art of record to modify the drape as disclosed in claims 1-13 of co-pending U.S. Patent Application Serial No. 11/298,251 as suggested by Examiner Jackson. However, even though Applicants disagree with Examiner Jackson's position, Applicants will consider filing a terminal disclaimer in the present application and/or co-pending U.S. Patent Application Serial No. 11/298,251 as necessary to avoid the possibility of double patenting.

Previously presented claims 21 and 23 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-20 of co-pending U.S. Patent Application Serial No. 11/298,251 in view of Grier-Idris and Keusch. Applicants respectfully submit that there is no suggestion in the art of record to modify the drape as disclosed in claims 18-20 of co-pending U.S. Patent Application Serial No. 11/298,251 as suggested by Examiner Jackson. However, even though Applicants disagree with Examiner Jackson's position, Applicants will consider filing a terminal disclaimer in the present application and/or co-pending U.S. Patent Application Serial No. 11/298,251 as necessary to avoid the possibility of double patenting.

Previously presented claim 24 was provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-20 of co-pending U.S. Patent Application Serial No. 11/298,251 in view of U.S. Patent No. 5,562,107 issued to Lavender et al. (hereinafter, "Lavender"). Applicants respectfully submit that there is no suggestion in the art of record to modify the drape as disclosed in claims 18-20 of co-pending U.S. Patent Application Serial No. 11/298,251 as suggested by Examiner Jackson. However, even though Applicants disagree with Examiner Jackson's position, Applicants will consider filing a terminal disclaimer in the present application and/or co-pending U.S. Patent Application Serial No. 11/298,251 as necessary to avoid the possibility of double patenting.

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II. Prior Art Rejections:

Rejection of Previously Presented Claims 1-4, 6, 9, 15-20 and 24-30 Under 35 U.S.C.
§102(b) In View Of U.S. Patent No. 5,197,493 (Grier-Idris)

Previously presented claims 1-4, 6, 9, 15-20 and 24-30 were rejected under 35 U.S.C. §102(b) as being anticipated by Grier-Idris. This rejection is respectfully traversed.

In order for the disclosure of Grier-Idris to anticipate Applicants' claimed invention, the disclosure of Grier-Idris must disclose each and every claim feature. *See, Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). *See also, Finnigan Corp. v. International Trade Commission*, 180 F.3d 1354, 1365, 51 USPQ2d 1001, 1009 (Fed. Cir. 1999) in which the Court states "In order to establish anticipation, a prior art reference must disclose every feature of the claimed invention."

The disclosure of Grier-Idris fails to disclose, teach, or suggest at least the following claim features recited in independent claims 1, 17, 29 and 30:

- (1) a covering for an aseptic treatment site comprising a transparent cover which is removably affixed in substantially aseptic covering relation relative to an aperture (claim 1);
- (2) a covering for an aseptic treatment site comprising a transparent cover defining a cavity over an aseptic treatment site when the transparent cover is disposed in covering relation relative to an aperture surrounding the aseptic treatment site, the cavity representing an empty space bound by (i) a lower surface of the transparent cover, (ii) a peripheral edge of a substrate along walls of the aperture, and (iii) an upper surface of the aseptic treatment site on a patient (claim 1);
- (3) a covering for an aseptic treatment site comprising a flexible transparent cover hingedly affixed on a first surface of a flexible substrate (claim 17);
- (4) a covering for an aseptic treatment site comprising a flexible transparent cover which is repeatably moveable along a course of travel between (i) a first, covering position relative to an aperture, and which permits observation of the aseptic treatment site, to (ii) a second, uncovered position relative to the aperture, and which permits access to the aseptic treatment site, and back to the first, covering position without contacting an area bound by the aperture (claim 17);
- (5) a covering for an aseptic treatment site comprising a transparent cover having an

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upper surface and a lower surface, the lower surface having a pattern of adhesive thereon for releasably adhesively affixing the transparent cover to a substrate, wherein a portion of the lower surface of the transparent cover that extends over an aperture is free of adhesive (claim 29); and

(6) a covering for an aseptic treatment site comprising (i) a first region of a substrate having opposite first and second surfaces, the first region defining an aperture which permits access to and surrounds a treatment site on a patient in combination with (ii) a second region of the substrate which is releasably attached to and surrounds the first region, wherein the second region is detachable from the first region so as to leave the first region on the patient and around the treatment site (claim 30).

Since the disclosure of Grier-Idris fails to disclose each and every claim feature recited in Applicants' independent claims 1, 17, 29 and 30, the disclosure of Grier-Idris cannot anticipate independent claims 1, 17, 29 and 30. Since claims 2-4, 6, 18-19 and 24-26 depend from independent claims 1 and 17 and recite additional claim features, the disclosure of Grier-Idris cannot anticipate dependent claims 2-4, 6, 18-19 and 24-26 (previously presented claims 9, 15-16, 20 and 27-28 have been canceled). Accordingly, withdrawal of this rejection is respectfully requested.

In the January 03, 2007 Office Action, Examiner Jackson argues that the disclosure of Grier-Idris discloses an incise system comprising a first region (10) and a selectively detachable second region (11) separated by perforations. Specifically, Examiner Jackson states on page 8, lines 9-20:

Grier-Idris discloses an incise system (10), comprising a flexible substrate defining an aperture permitting selective access to an aseptic treatment site (fig.3), a transparent cover borne by the substrate (col.1, lines 14-16) and which is irremovably affixed in aseptic covering relative to the aperture (fig. 3), a first (10) and second (11) region selectively detachable (col. 3, lines 13-19) wherein the second region (11) comprises a disposable sterile drape. The drape is presumed to be sterile because modern surgical drapes are inherently sterile to prevent unnecessary infections. Perforations surround the first region (10) and allow for the first region (10) to be separated from the second region (11). The first region (10) has a first portion (26) that defines the fenestration, and a second portion (14) detachable from the second region (11), wherein the first (26) and second (14) portions are made of the same polymeric material (col. 1, lines 14-16).

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It should be noted that Grier-Idris does not disclose a first region (10) and a selectively detachable second region (11) separated by perforations. Applicants note that “13” in FIG. 3 of Grier-Idris represents the outer boundary of primary fenestration 13 within mainsheet 11, not perforations. See, for example, column 3, lines 13-23. The only line of perforations disclosed in Grier-Idris is represented by “28”. Line of perforations 28 in the disclosure of Grier-Idris separates a first portion (26) of first layer 12 from a second portion of first layer 12. See, for example, column 3, lines 33-43.

Rejection of Previously Presented Claims 5, 7 and 22 Under 35 U.S.C. §103(a) In View Of Grier-Idris In Combination With Levitt

Previously presented claims 5, 7 and 22 were rejected under 35 U.S.C. §103(a) as being unpatentable over Grier-Idris in view of Levitt. This rejection is respectfully traversed.

Claim 5 depends from independent claim 1 discussed above. Previously presented claims 7 and 22 have been canceled.

Like the disclosure of Grier-Idris, the disclosure of Levitt fails to disclose, teach, or suggest at least the following claim features recited in independent claim 1:

- (1) a covering for an aseptic treatment site comprising a transparent cover which is removably affixed in substantially aseptic covering relation relative to an aperture; and
- (2) a covering for an aseptic treatment site comprising a transparent cover defining a cavity over an aseptic treatment site when the transparent cover is disposed in covering relation relative to an aperture surrounding the aseptic treatment site, the cavity representing an empty space bound by (i) a lower surface of the transparent cover, (ii) a peripheral edge of a substrate along walls of the aperture, and (iii) an upper surface of the aseptic treatment site on a patient.

Applicants respectfully submit that the proposed combination of the teaching of Grier-Idris with the teaching of Levitt, even if proper, fails to disclose, teach or suggest Applicants’ claimed invention as recited in independent claim 1. Since claim 5 depends from independent claim 1 and recites additional claim features, the proposed combination of the teaching of Grier-Idris with the teaching of Levitt, even if proper, fails to disclose, teach or suggest Applicants’ claimed invention as recited in dependent claim 5. Accordingly, withdrawal of this rejection is respectfully requested.

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Rejection of Previously Presented Claims 8, 10-14 and 23 Under 35 U.S.C. §103(a) In View Of Grier-Idris In Combination With Keusch

Previously presented claims 8, 10-14 and 23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Grier-Idris in view of Keusch. This rejection is respectfully traversed.

Claims 11-14 depend from independent claim 1 discussed above. Previously presented claims 8, 10 and 23 have been canceled.

Like the disclosure of Grier-Idris, the disclosure of Keusch fails to disclose, teach, or suggest at least the following claim features recited in independent claim 1:

- (1) a covering for an aseptic treatment site comprising a transparent cover which is removably affixed in substantially aseptic covering relation relative to an aperture; and
- (2) a covering for an aseptic treatment site comprising a transparent cover defining a cavity over an aseptic treatment site when the transparent cover is disposed in covering relation relative to an aperture surrounding the aseptic treatment site, the cavity representing an empty space bound by (i) a lower surface of the transparent cover, (ii) a peripheral edge of a substrate along walls of the aperture, and (iii) an upper surface of the aseptic treatment site on a patient.

Applicants respectfully submit that the proposed combination of the teaching of Grier-Idris with the teaching of Keusch, even if proper, fails to disclose, teach or suggest Applicants' claimed invention as recited in independent claim 1. Since claims 11-14 depend from independent claim 1 and recite additional claim features, the proposed combination of the teaching of Grier-Idris with the teaching of Keusch, even if proper, fails to disclose, teach or suggest Applicants' claimed invention as recited in dependent claims 11-14. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection of Previously Presented Claim 21 Under 35 U.S.C. §103(a) In View Of Grier-Idris In Combination With U.S. Patent No. 5,538,012 (Wiedner)

Previously presented claim 21 was rejected under 35 U.S.C. §103(a) as being unpatentable over Grier-Idris in view of U.S. Patent No. 5,538,012 issued to Wiedner. This rejection is moot given that previously presented claim 21 has been canceled.

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III. New Claims 31-42:

New claims 31-42 are directed to various embodiments of Applicants' invention. New claims 31-35 depend from independent claims 1, 17, 29 and 30 discussed above, and recite additional claim features.

New claim 36 is directed to a disposable drape comprising (i) a first region comprising first region material having a first region outer periphery and an aperture positioned within the first region outer periphery and surrounded by the first region material, wherein the aperture is sized so as to surround an aseptic treatment site on a patient so that the aseptic treatment site is accessible through the aperture; and (ii) a second region surrounding the first region outer periphery of the first region, the second region being detachably joined to the first region material such that detachment of the second region from the first region does not alter an outer periphery of the aperture. New claims 37-42 depend from new independent claim 36 and recite additional claim features.

It should be noted that the art of record fails to disclose, teach or suggest a drape as recited in new independent claim 36. In particular, the art of record fails to disclose, teach or suggest a disposable drape comprising a first region comprising first region material having a first region outer periphery and an aperture positioned within the first region outer periphery and surrounded by the first region material, and a second region surrounding the first region outer periphery of the first region, the second region being detachably joined to the first region material such that detachment of the second region from the first region does not alter an outer periphery of the aperture as recited in new independent claim 36.

Support for new claims 31-42 may be found in at least the following locations of Applicants' original specification: page 9, lines 1-4, and FIG. 5 (claims 31-33); page 7, lines 10-16, and FIG. 2 (claims 34 and 37); page 8, lines 15-22, and FIG. 5 (claim 35); page 7, lines 10-16, FIG. 2 and original claim 3 (claims 36-37); page 8, lines 15-22, FIG. 5 and original claim 3 (claim 38); page 9, lines 1-4, FIG. 5 and original claim 3 (claim 39); page 8, lines 6-11, FIG. 5 and original claim 3 (claim 40); and page 8, line 6 to page 9, line 12, page 11, lines 12-19, and original claim 3 (claims 41-42).

Applicants respectfully submit that new claims 31-42 are patentable over the art

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of record for at least the reasons given above.

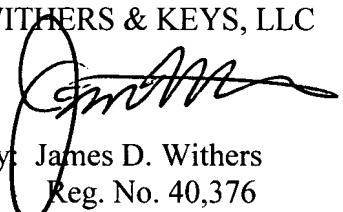
IV. Conclusion:

For at least the reasons given above, Applicant submits that claims 1-6, 11-14, 17-19, 24-26 and 29-42 define patentable subject matter. Accordingly, Applicants respectfully request allowance of these claims.

Should Examiner Jackson believe that further action is necessary to place the application in better condition for allowance, Examiner Jackson is respectfully requested to contact Applicants' representative at the telephone number listed below.

Applicants would greatly appreciate a telephone or personal interview with Examiner Jackson prior to the next office communication in order to expedite prosecution of the present application. Examiner Jackson is respectfully requested to contact Applicants' representative at the telephone number listed below.

No additional fees are believed due; however, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 503025.

Respectfully submitted,
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